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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

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DEPT 430 M S 27 4 A
AMGEN INC
ONE AMGEN CENTER DRIVE
THOUSAND OAKS CA 91320-1789

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/079,569	05/14/98	003	BUDENS, R 1648	09/17/98

First Named Applicant	BOYLE, WILLIAM J.

TITLE OF INVENTION: ANTIBODIES SPECIFIC FOR OSTEOPROTEGERIN BINDING PROTEINS AND METHOD OF USE (AS AMENDED)

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 A-451D	435-007.240	J08	UTILITY	NO	$1320.00	12/17/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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EXAMINER'S AMENDMENT

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Robert B. Winter, on September 14, 1998.

IN THE SPECIFICATION

Please amend the Title to read as follows:

--ANTIBODIES SPECIFIC FOR OSTEOPROTEGERIN BINDING PROTEINS AND METHODS OF USE--

At page 5, line 3, delete "Figure 1" and insert --Figures 1A-1H--.

IN THE CLAIMS:

Please cancel claims 1-21 and 25-33 without prejudice.

Applicant should further note the following comments from the Examiner.

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(h), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> **"The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee."**

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

The Brief Description of the Drawings is inconsistent with the originally filed drawings, i.e., there is no description of Figures 1A-1H. Correction is required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, and 4-13, drawn to nucleic acids encoding osteoprotegerin binding protein, classified in class 536, subclass 23.1.

II. Claims 3, 4-21, 25, 29, and 30, drawn to osteoprotegerin binding protein and method of detecting osteoprotegerin, classified in class 530, subclass 350.

III. Claims 22-24, drawn to antibodies against osteoprotegerin binding protein and method of detecting osteoprotegerin binding protein, classified in class 530, subclass 387.1.

IV. Claims 26 and 27, drawn to a method of using osteoprotegerin binding protein to assess candidate compounds to bind to osteoprotegerin binding protein, classified in class 435, subclass 7.1.

V. Claim 28, drawn to a method of using nucleic acids encoding osteoprotegerin binding protein, classified in class 514, subclass 44.

VI. Claim 32, drawn to a method of treating bone diseases with osteoprotegerin binding protein, classified in class 514, subclass 2.

VII. Claim 33, drawn to a method of treating bone diseases with antibody against osteoprotegerin binding protein, classified in class 424, subclass 130.1.

Claim 31 links Inventions VI and VII. This claim will be examined with Invention VI or Invention VII if Invention VI or VII is elected.

The inventions are distinct, each from the other because:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I and the antibody of Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in a hybridization assay, for example.

The nucleic acids of Invention I is not used in any of the methods of Inventions IV, VI, or VII. Therefore, Invention I is

patentably distinct from Inventions IV, VI, and VII.

Inventions II and IV or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in either Inventions IV or VI or to make antibodies, for example.

The osteoprotegerin binding protein of Invention II is not used in the methods of Inventions V or VII. Therefore, Invention II is patentably distinct from Inventions V and VII.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in purifying osteoprotegerin binding protein, for example.

The antibodies of Invention III is not used in any of the methods of Inventions IV, V, or VI. Therefore, Invention III is patentably distinct from Inventions IV, V, and VI.

The methods of Inventions IV-VII utilize different agents and/or are comprised of wholly different steps and have wholly different end results. Therefore, the methods of Inventions IV-VII are patentably distinct one from the other.

During a telephone conversation with Mr. Robert B. Winter on September 14, 1998, a provisional election was with traverse to prosecute the invention of Group III, claims 22-24. Because Applicant have accepted allowance of these elected claims on first action, this election is considered to be made without traverse.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner

by telephone are unsuccessful, the Examiner's supervisor, Don Adams, can be reached at (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
September 14, 1998